



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2020-0738; FRL-10019-82]

Chemical Category for Octahydro-tetramethyl-naphthalenyl-ethanone (OTNE); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on a manufacturer request for a risk evaluation under the Toxic Substances Control Act (TSCA) of ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), and ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl) (collectively, “OTNE”). The request was made by International Flavors and Fragrances, Inc. (IFF), Privi Organics USA Corporation (Privi), and DRT America, Inc. (DRT) through the OTNE Consortium. EPA conducts risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations, under the conditions of use. In the docket associated with this request is the manufacturer request for an EPA-conducted risk evaluation and possible additional conditions of use EPA has identified for inclusion within the scope of a risk evaluation of OTNE. EPA specifically invites public comment on the inclusion of any additional conditions of use and potentially exposed or susceptible subpopulations. The Agency is in the process of broadly re-examining how it intends to implement these and other provisions of amended TSCA including determining how new executive orders and other direction provided by the Biden-Harris Administration will be

addressed. This process would benefit greatly from stakeholder feedback. After considering comments received in response to this solicitation, EPA will determine whether to grant or deny the manufacturer request. All TSCA risk evaluations, whether EPA-initiated or manufacturer-requested, will be conducted in the same manner.

DATES: Comments must be received on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0738, through the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room were closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jeffrey Putt, Existing Chemicals Risk Management Division (Mail Code 7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3703; email address: putt.jeffrey@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this apply to me?

This notice is directed to the public in general and may be of interest to persons who currently or may manufacture (including import), process, distribute, use, and/or dispose of OTNE. The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested in these risk evaluations, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

TSCA section 6(b) requires that EPA conduct risk evaluations on existing chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations. 15 U.S.C. 2605(b). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(iii). The specific risk evaluation process is set out in 40 CFR part 702 and summarized on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

TSCA section 6(b) also allows manufacturers of a chemical substance to request an EPA-conducted risk evaluation on the chemical substance. TSCA required EPA to develop the form and manner under which these requests must be made, and the criteria for which EPA will determine whether to grant a request. These requirements and criteria are set out in 40 CFR 702.37.

Under 40 CFR 702.37(e)(3), EPA is required to assess whether the circumstances identified in a manufacturer request for a risk evaluation constitute conditions of use (as defined under TSCA section (3)(4) and implementing regulations at 40 CFR 702.33), and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical

substance. EPA will also assess what, if any, additional conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will conduct these assessments based on the same considerations applied in the same manner as it would for a risk evaluation in the EPA-initiated risk evaluation process.

No later than 60 business days after receiving a manufacturer request for risk evaluation that EPA has determined to be facially complete (meeting the criteria set forth in 40 CFR 702.37(e)(1)), EPA is required to submit for publication the receipt of the request in the Federal Register, open a public docket for the request (which must contain the manufacturer request and EPA's possible additional conditions of use), and provide no less than 45 calendar days for public comment. This notice identifies the docket containing the manufacturer request, EPA's possible additional conditions of use, and the basis for including those possible additional conditions of use. During the public comment period, the public may submit comments and information relevant to the requested risk evaluation, as well as the additional possible conditions of use EPA is including in the docket.

After the comment period closes, the Agency has up to 60 days to either grant or deny the request to conduct a risk evaluation under 40 CFR 702.37(e)(6). EPA will review the request along with any additional information received during the comment period, and grant the request if it determines the request meets all of the following requirements listed under 40 CFR 702.37(e)(6)(ii):

- The circumstances identified in the request constitute conditions of use that warrant inclusion in a risk evaluation for the chemical substance;
- EPA has all the information needed to conduct such risk evaluation on the conditions of use that were the subject of the request; and
- All other criteria and requirements of 40 CFR 702.37 have been met.

C. What action is EPA taking?

EPA is announcing the availability of and soliciting public comment on a manufacturer

request for a risk evaluation of OTNE under TSCA section 6(b) that is described in detail in Unit II. Also available in the docket associated with this request are the manufacturer request and possible additional conditions of use EPA identified for inclusion in a risk evaluation of OTNE. This notice satisfies 40 CFR 702.37(e)(4).

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Summary of this Manufacturer Request

On November 20, 2020, EPA received a complete manufacturer request for a TSCA risk evaluation of OTNE that was made by IFF, Privi, and DRT, through the OTNE Consortium. After determining the request was facially complete (i.e., EPA determined that the request appeared to be consistent with the requirements in 40 CFR 702.37(b) through (d), such as including all the necessary information in those paragraphs), EPA notified the public of the receipt of the request on December 8, 2020 via a listserv announcement to stakeholders.

A. What is OTNE?

OTNE is used as a fragrance ingredient. The four chemical substances in this chemical category are listed on the TSCA Inventory as: ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-

naphthalenyl), ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), and ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl). The associated Chemical Abstracts Service Registry Numbers (CASRN) are 54464-59-4, 54464-57-2, 68155-67-9, and 68155-66-8, respectively. TSCA section 26(c) provides for EPA to take action on a category of chemical substances whenever authorized or required by TSCA to take action on a chemical substance. 15 U.S.C. § 2625(c). EPA is treating these four CASRN (54464-59-4, 54464-57-2, 68155-67-9, and 68155-66-8) as a category of chemical substances for purposes of this manufacturer-requested risk evaluation.

B. What are the conditions of use?

The manufacturer request for a risk evaluation of OTNE identifying conditions of use of interest to the manufacturer is included in docket EPA-HQ-OPPT-2020-0738. Subject to further analysis and public comment, EPA anticipates including activities identified in the request as conditions of use in the risk evaluation of OTNE.

EPA has identified additional conditions of use pursuant to 40 CFR 702.37(e)(3), which are also included in docket EPA-HQ-OPPT-2020-0738.

III. Request for Comment

The docket associated with this request contains the manufacturer request (excluding information claimed as CBI), EPA's possible additional conditions of use as described 40 CFR 702.37(e)(3), and the basis for these possible additions. During the comment period, the public may submit comments and information relevant to the requested risk evaluation; in particular, commenters are encouraged to identify any information not included in the request that the commenters believe would be needed to conduct a risk evaluation, and to provide any other information relevant to EPA's possible additional conditions of use, such as information on other conditions of use of the chemical substances than those included in the request or in EPA's possible additional conditions of use. 40 CFR 702.37(e)(4). In addition, at any time prior to the end of the comment period, the requesting manufacturer(s) may supplement the original request

with any new information it receives. 40 CFR 702.37(e)(5).

Authority: 15 U.S.C. 2601 *et seq.*

Jane Nishida,

Acting Administrator.

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